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| FORM PTO-1390 (Modified) U.S. PATENT AND TRADEMARK OFFICE; U.S. DEPARTMENT OF COMMERCE (REV. 7-2005) | | ATTORNEY'S DOCKET NUMBER PB60536USW |
| TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371 | | U.S. APPLICATION NO. (If known, see 37 CFR 1.5) <div style="font-size: 1.5em; font-weight: bold; text-align: center;">10/575208</div> |
| INTERNATIONAL APPLICATION NO. PCT/US2004/033521 | INTERNATIONAL FILING DATE 12 October 2004 | PRIORITY DATE CLAIMED 14 October 2003 |
| TITLE OF INVENTION Process for Preparing a Co-Precipitate of a Non-Crystalline Solid Drug Substance | | |
| APPLICANT(S) FOR DO/EO/US BARRETT, Roger; WARD, Richard, Anthony | | |
| Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information: | | |
| <ol style="list-style-type: none"> 1. <input checked="" type="checkbox"/> This is a FIRST submission of items concerning a submission under 35 U.S.C. 371. 2. <input type="checkbox"/> This is a SECOND or SUBSEQUENT submission of items concerning a submission under 35 U.S.C. 371. 3. <input checked="" type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (24) indicated below. 4. <input checked="" type="checkbox"/> The US has been elected (Article 31). 5. <input checked="" type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371 (c)(2)) <ol style="list-style-type: none"> a. <input type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau). b. <input type="checkbox"/> has been communicated by the International Bureau. c. <input checked="" type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US). 6. <input type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)). <ol style="list-style-type: none"> a. <input type="checkbox"/> is attached hereto. b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4). 7. <input checked="" type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3)) <ol style="list-style-type: none"> a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau). b. <input type="checkbox"/> have been communicated by the International Bureau. c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired. d. <input checked="" type="checkbox"/> have not been made and will not be made. 8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). 9. <input checked="" type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)). 10. <input type="checkbox"/> An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)). 11. <input type="checkbox"/> A copy of the International Preliminary Examination Report (PCT/IPEA/409). 12. <input checked="" type="checkbox"/> A copy of the International Search Report (PCT/ISA/210). | | |
| Items 13 to 23 below concern document(s) or information included: | | |
| <ol style="list-style-type: none"> 13. <input checked="" type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98. 14. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. 15. <input checked="" type="checkbox"/> A FIRST preliminary amendment. 16. <input type="checkbox"/> A SECOND or SUBSEQUENT preliminary amendment. 17. <input type="checkbox"/> A substitute specification. 18. <input checked="" type="checkbox"/> A power of attorney and/or change of address letter. 19. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 - 1.825. 20. <input type="checkbox"/> A second copy of the published International Application under 35 U.S.C. 154(d)(4). 21. <input type="checkbox"/> A second copy of the English language translation of the International Application under 35 U.S.C. 154(d)(4). 22. <input checked="" type="checkbox"/> Express Mail Label No. EV 332064632 US | | |

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| U.S. APPLICATION NO (if known, see 37 CFR 1.5) <div style="font-size: 24pt; font-weight: bold; text-align: center;">10/575208</div> | INTERNATIONAL APPLICATION NO. <div style="font-weight: bold; text-align: center;">PCT/US2004/033521</div> | ATTORNEY'S DOCKET NUMBER <div style="font-weight: bold; text-align: center;">PB60536USW</div> |
| 23. Other items or information: a) PCT Cover Page b) PCT Request | | |
| The following fees have been submitted: | | CALCULATIONS PTO USE |
| 24. <input checked="" type="checkbox"/> Basic national fee \$300 | | \$ 300.00 |
| 25. <input checked="" type="checkbox"/> Examination fee (37 CFR 1.492(c)) If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article as an International Searching Authority. \$0 All other situations. \$200 | | \$ 200.00 |
| 26. <input checked="" type="checkbox"/> Search fee (37 CFR 1.492(b)) If the written opinion of the ISA/US or the International preliminary examination report by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4). ... \$0 Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the as an International Searching Authority. \$100 International Search Report prepared by an ISA other than the US and provided to the previously communicated to the US by the IB. \$400 All other situations. \$500 | | \$ 400.00 |
| TOTAL OF 24, 25 and 26 = | | \$ 900.00 |
| <input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(i)). The fee is \$250 for each additional 50 sheets of paper or fraction thereof. | | |
| Total Sheets | Extra Sheets | Number of each additional 50 or fraction thereof (round up to a whole) |
| - 100 = | 0 | /50 = |
| 0 | | x \$250.00 |
| Surcharge of \$130.00 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)). | | \$ 0.00 |
| CLAIMS | NUMBER FILED | NUMBER EXTRA |
| Total claims | 20 - 20 = | 0 |
| Independent claims | 10 - 3 = | 7 |
| MULTIPLE DEPENDENT CLAIMS (if applicable) <input type="checkbox"/> + \$360.00 | | \$ 0.00 |
| TOTAL OF ABOVE CALCULATIONS = | | \$ 2,300.00 |
| <input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2. | | \$ 0.00 |
| SUBTOTAL = | | \$ 2,300.00 |
| Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)). | | \$ 0.00 |
| TOTAL NATIONAL FEE = | | \$ 2,300.00 |
| Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40 per property + | | \$ 0.00 |
| TOTAL FEES ENCLOSED = | | \$ 2,300.00 |
| | | Amount to be \$ |
| | | Amount to be \$ |

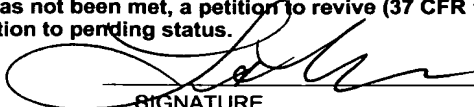
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

- a. ☐ A check in the amount of \$ _____ to cover the above fees is enclosed.
- b. ☒ Please charge my Deposit Account No. 07-1392 in the amount of \$ \$2,300.00 to cover the above fees.
A duplicate copy of this sheet is enclosed.
- c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 07-1392. A duplicate copy of this sheet is enclosed.
- d. ☐ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. **Credit card information should not be included on this form.** Provide credit card information and authorization on PTO-2038.

NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.

SEND ALL CORRESPONDENCE TO:

23347



SIGNATURE

Lorie Ann Morgan

NAME

38,181

REGISTRATION NUMBER

10 April 2006

DATE

10/575208

CERTIFICATE OF MAILING BY "EXPRESS MAIL" (37 CFR 1.10)

Applicant(s): Barrett et al.

APR 9 2006

PCT/PTO

10 APR 2006

PB60536USW

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|-----------------------------------|--------------------------------------|----------|-----------------------|----------------|
| Application No. To Be Assigned | Filing Date Concurrently Herewith | Examiner | Customer No. 23347 | Group Art Unit |
|-----------------------------------|--------------------------------------|----------|-----------------------|----------------|

Invention: Process for Preparing a Co-Precipitate of a Non-Crystalline Solid Drug Substance

I hereby certify that the following correspondence:

National Phase Application w/accompanying papers

(Identify type of correspondence)

is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on

April 10, 2006
(Date)

Valerie L. Phillips

(Typed or Printed Name of Person Mailing Correspondence)

Valerie L. Phillips
(Signature of Person Mailing Correspondence)

EV332064632US

(Express Mail Mailing Label Number)